

Notice of Allowability

Application No.

09/882,523

Applicant(s)

MINARIK ET AL.

Examiner

Art Unit

Ling-Siu Choi

1713

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Amendment after Final.
2. ☒ The allowed claim(s) is/are 1-3 and 5-17.
3. ☒ The drawings filed on 18 October 2001 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date <u>12/18/02</u> | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

DETAILED ACTION

1. This Office Action is in response to the Amendment after Final Rejection filed December 14, 2004. claims 1-17 are now pending.

Examiner's Amendment

2. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CAR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. David Schneck on January 21, 2005.

3. The application has been amended as follows:

Cancel claim 4;

Claim 1, line 8, change "polyvinylpyrrolidone;" to --polyvinylpyrrolidone using pressure loading at a pressure not greater than 100 psi;--.

Allowable Subject Matter

4. Claims 1-3 and 5-17 are allowed.

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5. The following is an examiner's statement of reasons for allowance:

The present claims are allowable over the closest references: Barry et al. [Journal of Chromatography A, 732, 159-166(1996)], Zhu et al. (US 5,089,111), and Madabhushi et al. (US 5,567,292).

The present invention relates to a method for electrophoretic separation of a mixture of oligonucleotide fragments having different lengths between 0 and 100 bases, comprising

A	filling a microchannel with a separation media comprising non-entangled pyvinylpyrrolidone which has a pressure loading at a pressure \leq 100 psi
B	injecting the mixture of oligonucleotide fragments into a first end of the microchannel
C	applying an electrophoretic current sufficient to cause the oligonucleotide fragments to migrate through the separation media
D	detecting separated oligonucleotide fragments at an end removed from the injection end

(summary of claim 1)

Barry et al. disclose a method to separate oligonucleotides by capillary electrophoresis in a polyvinylpyrrolidone matrix in a coated fused-silica column, wherein the polyvinylpyrrolidone is in a pseudo phase formed through hydrogen bonding, dipole-dipole, dipole-induced dipole, and hydrophobic interactions and wherein the oligonucleotide has 4-6 bases in length (abstract, page 160, first col.). Barry et al. further disclose that an electrospray mass spectrometry is used to identify oligonucleotides (page 159, col. 2). However, Barry et al. do not teach or fairly a method to use a pressure loading at a pressure \leq 100 psi.

Zhu et al. disclose a method to separate a mixture of polynucleotide chains having about 10 to about 10,000 base pairs, the method comprising electrophoretically passing the mixture through a capillary column containing a gel-free aqueous solution of a substantially linear polymer which can be polyvinylpyrrolidone, wherein the detection is performed on line in the capillary by UV absorption (col. 3, line 9; col. 4, lines 63-64; claim 16). However, Zhu et al. do not teach or fairly a method to use a pressure loading at a pressure ≤ 100 psi.

Madabhushi et al. a method to separate different-sized polynucleotides by electrophoresis in an uncoated silica capillary, the method comprising the steps of (a) providing an uncoated silica capillary containing a separation medium containing one or more uncharged water-soluble silica-adsorbing polymer such as polyvinylpyrrolidone, (b) loading a sample of different-sized polynucleotide in the uncoated silica capillary, and (c) applying an electrical field between the first and second ends of the uncoated silica capillary so that the different-sized polynucleotides in the sample migrate through the uncoated silica capillary, wherein the detection is based on UV absorption, fluorescence emission, conductance, radioactive emission; the nucleotide more preferably has about 20 to 600 bases; denaturants may be used to prevent the formation of duplexes or secondary structures in polynucleotides (col. 8, lines 11-14 and 22-26; claims 4 and 10). However, Madabhushi et al. do not teach or fairly a method to use a pressure loading at a pressure ≤ 100 psi.

In light of the above discussion, it is evident as to why the present claims are patentable over the prior art.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue

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fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ling-Siu Choi whose telephone number is 571-272-1098.

If attempt to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Wu, can be reach on 571-272-1114.

Ling-Sui Choi

**LING-SUI CHOI
PRIMARY EXAMINER**

January 25, 2005